LAW OFFICES OF
FAY KAPLUN & MARCIN, LLP
INTELLECTUAL PROPERTY LAW

150 BROADWAY, SUITE 702
NEW YORK, NEW YORK 10038
PHONE: (212) 619-6000
FAX : (212) 208-6819
WWW.FKMIPLAW.COM

FACSIMILE COVER SHEET

FAX NO : (571) 273-8300

TO : Mail Stop: Appeal Brief-Patent
Commissioner for Patents

FROM : Oleg F. Kaplun, Esq. of Fay Kaplun & Marcin, LLP

DATE : July 1, 2008

SUBJECT : U.S. Patent Appln. Serial No. 10/694,846
for *Osteosynthetic device*
Inventor(s): Hehli et al.
Our Ref.: 10139/04602

NUMBER OF PAGES INCLUDING COVER : 19

MESSAGE:

Please see attached.

Thank you.

Attorney Docket No. 10139/04602 (00616-05PUS1)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s)	:	Hehli et al.
Serial No.	:	10/694,846
Filing Date	:	October 29, 2003
For	:	Osteosynthetic device
Group Art Unit	:	3733
Confirmation No.	:	2490
Examiner	:	Woodall, Nicholas W.

Mail Stop: Appeal Brief-Patent
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Certificate of Facsimile

I hereby certify that this correspondence is being deposited facsimile to:

Mail Stop: Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
(571) 273-8300

By: Date: July 1, 2008
Oleg F. Kaplun, Reg. No. 45,559

TRANSMITTAL

In support of the Notice of Appeal filed on May 5, 2008, please find an Appeal Brief for filing in the above-identified application. Please charge the Credit Card of Fay Kaplun & Marcin in the amount of $510.00 (PTO 2038 is enclosed herewith). The Commissioner is hereby authorized to charge the **Deposit Account of Fay Kaplun & Marcin, LLP No. 50-1492** for any additional fees. A copy of this paper is enclosed for that purpose.

Respectfully submitted,

Dated: July 1, 2008

By: _____
Oleg F. Kaplun (Reg. No. 45,559)

Fay Kaplun & Marcin, LLP
150 Broadway, Suite 702
New York, N.Y. 10038
(212) 619-6000 (telephone)
(212) 619-0276 (facsimile)

Attorney Docket No. 10139/04602 (00616-05PUS1)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s)	:	Hehli et al.
Serial No.	:	10/694,846
Filing Date	:	October 29, 2003
For	:	Osteosynthetic device
Group Art Unit	:	3733
Confirmation No.	:	2490
Examiner	:	Woodall, Nicholas W.

Mail Stop: Appeal Brief-Patent
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Certificate of Facsimile

I hereby certify that this correspondence is being deposited facsimile to:

Mail Stop: Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
(571) 273-8300

By: Date: July 1, 2008
Oleg F. Kaplun, Reg. No. 45,559

TRANSMITTAL

In support of the Notice of Appeal filed on May 5, 2008, please find an Appeal Brief for filing in the above-identified application. Please charge the Credit Card of Fay Kaplun & Marcin in the amount of $510.00 (PTO 2038 is enclosed herewith). The Commissioner is hereby authorized to charge the **Deposit Account of Fay Kaplun & Marcin, LLP No. 50-1492** for any additional fees. A copy of this paper is enclosed for that purpose.

Respectfully submitted,

Dated: July 1, 2008

By:
Oleg F. Kaplun (Reg. No. 45,559)

Fay Kaplun & Marcin, LLP
150 Broadway, Suite 702
New York, N.Y. 10038
(212) 619-6000 (telephone)
(212) 619-0276 (facsimile)

PATENT
Attorney Docket No.: 10139 - 04602

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	)	
	)	
Hehli et al.	)	
	)	
Serial No.: 10/694,846	)	Group Art Unit: 3733
	)	
Filed: October 29, 2003	)	Examiner: Nicholas W. Woodall
	)	
For: OSTEOSYNTHETIC DEVICE	)	**Board of Patent Appeals and Interferences**
	)	
	)	

Mail Stop: Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

In support of the Notice of Appeal filed May 5, 2008, and pursuant to 37 C.F.R. § 41.37, Appellants present this appeal brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 1 - 18 in the Final Office Action dated February 4, 2008. The appealed claims are set forth in the attached Claims Appendix.

07/02/2008 HMARZI1 00000058 10694846
01 FC:1402 510.00 OP

1. Real Party in Interest

This application is assigned to Synthes (U.S.A.) which is a wholly owned subsidiary of Synthes, Inc., the real party in interest.

2. Related Appeals and Interferences

A Pre-Appeal Brief Review was conducted in response to a Pre-Appeal Brief Request for Review filed on August 2, 2007. A Notice of Panel Decision was mailed on September 25, 2007 noting that claims 1 - 18 stand rejected over the prior art.

3. Status of the Claims

Claims 1 - 18 stand rejected in the Final Office Action. The final rejection of claims 1 - 18 is being appealed.

4. Status of Amendments

All amendments submitted by the Appellants have been entered.

5. Summary of Claimed Subject Matter

The present invention describes, as recited in claim 1, an osteosynthetic device comprising an intramedullary nail 1. (*See* Specification, p. 2, ¶ [0031]; Figs. 1 - 2). The intramedullary nail 1 has a longitudinal shape with a central axis 5, extending from a first end 2 to a second end 3. (*Id.*) The shape of the osteosynthetic device 1 is helical. (*Id.*)

6. Grounds of Rejection to be Reviewed on Appeal

I. Whether claims 1, 2, 7, 9, 13, 14 and 17 are unpatentable under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,626,613 to Schmieding (hereinafter "Schmieding").

II. Whether claims 8, 10 and 12 are unpatentable under 35 U.S.C. § 103(a) as obvious over Schmieding.

III. Whether claims 3 - 6, 11 and 15 - 16 are unpatentable under 35 U.S.C. § 103(a) as obvious over Schmieding.

IV. Whether claim 18 is unpatentable under 35 U.S.C. § 103(a) as obvious over Schmieding.

7. Argument

I. The Rejection of Claims 1, 2, 7, 9, 13, 14 and 17 Under 35 U.S.C. § 102(b) as Anticipated by Schmieding Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 1, 2, 7, 9, 13, 14 and 17 were rejected under 35 U.S.C. 102(b) as anticipated by Schmieding. (*See* 2/4/08 Office Action, pp. 2 - 3). The Examiner stated that Schmieding discloses a device having a longitudinal shape with a central axis, a first end, and a second end, wherein the device is helical. (*See* 2/4/08 Office Action, pp. 2 - 3). The Examiner further asserts that the device of Schmieding is capable of being used as an

intramedullary nail in the bone of an organism smaller than a human. (*See* 4/4/07 Office Action, p. 5). In the Advisory Action dated June 13, 2007, the Examiner also statd that the term "intramedullary" is a functional, not structural, adjective and that, therefore, Schmieding reads on the structural limitations of claim 1. (*See* 6/13/07 Advisory Action, p. 3).

B. Schmieding does not Disclose an Intramedullary Nail

Schmieding purports to describe a corkscrew suture anchor 2 for reattaching soft tissue to bone. (*See* Schmieding, col. 1, ll. 12 - 16; col. 3, ll. 12 - 16). The suture anchor 2 has a sharp point 10 adapted to pierce bone and form a tunnel within bone, and a suture eye 8 for receiving a suture. (*Id.*, col. 3, ll. 18 - 24, col. 3, ll. 61 - 63; Fig. 1).

Claim 1 recites an osteosynthetic device comprising "*an intramedullary nail* having a longitudinal shape with a central axis, a first end, and a second end, wherein the shape of the device is helical." (Emphasis added).

Initially, it is respectfully submitted that Schmieding does not teach an "intramedullary nail," as recited in claim 1. The term "intramedullary nail" is clearly recognized by those skilled in the art as defining a specific device having defined structural qualities -- i.e., the nail must be sized and shaped to conform to the medullary canal into which it will be inserted, the materials must be biocompatible and strong enough to absorb the stresses to which the bone will be exposed, etc. The specification of the present application uses this term "intramedullary nail" completely consistently with this meaning of the term as it is understood by those skilled in the

art. (*See* Specification, ¶ [0002], [0003], [0007], [0012], [0015], [0031]). A nail is not an intramedullary nail simply because it can fit in the medullary canal. Although a penny nail or horseshoe nail could fit in the medullary canal, this does not make such a nail an intramedullary nail as neither of these nails has the structure necessary to perform the function of an intramedullary nail. Although the term 'intramedullary nail' does indicate the intended use of the item, it also defines its structure in the same manner as does the term "horseshoe nail." It is respectfully submitted that the Examiner's assertion that this term is solely an indication of intended use ignores the realities of this technology and the way in which this term is understood by those skilled in the art. It is therefore submitted that the device of Schmieding is in no way intended for use in the intramedullary canal and furthermore, this device does not have the required structural attributes to function as an intramedullary nail and thus does not meet the limitation of "intramedullary nail," recited in claim 1.

Furthermore, even without the structural implications of the specific term "*intramedullary* nail," Schmieding still fails to show a "nail" of any kind. Specifically, Schmieding shows a corkscrew suture anchor which is in no way a nail. (*See* Schmieding, Abstract). Those skilled in the art would not be motivated to interpret the corkscrew suture anchor of Schmieding as a "nail," as recited in claim 1, but rather as a screw.

It is further submitted that the Examiner's assertion that the Schmieding suture anchor "is capable of being used as an intramedullary nail if one so desired" is unfounded. (*See* 6/13/07 Advisory Action, p. 2). There is nothing in Schmieding that makes such a claim and in fact, this

structure is entirely unsuitable for this purpose. Thus, it is respectfully submitted that this assertion is based wholly on speculation by the Examiner, a misunderstanding of the meaning of the term "intramedullary nail" and a failure to consider or understand the function of the structure as indicated in this application and as understood generally by those skilled in the art. Specifically, there is absolutely nothing in Schmieding that indicates that the suture anchor 2 may be inserted into the medullary canal for any purpose whatsoever much less to serve as an intramedullary nail.

It is therefore respectfully submitted that the Examiner has not made a *prima facie* case of anticipation of independent claim 1, and that the rejection of claim 1, along with the rejections of dependent claims 2, 7, 9, 13, 14, and 17, should be withdrawn.

II. The Rejection of Claims 8, 10 and 12 Under 35 U.S.C. § 103(a) as Obvious over Schmieding Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 8, 10 and 12 were rejected under 35 U.S.C. 103(a) as unpatentable over Schmieding. (*See* 2/4/08 Office Action, p. 3). The Examiner stated that Schmieding discloses the claimed invention except for the cross-section orthogonal to the central axis having a shape of a square, star, rectangle, or a rectangle with rounded edges but that this would be an obvious modification to the Schmieding device. (*Id.*)

B. Schmieding Does Not Disclose an Intramedullary Nail as recited in claim 1

Claim 1 has been recited above and discussed with reference to the 35 U.S.C. § 102(b) rejection. Claims 8, 10 and 12 depend from and therefore include all the limitations of independent claim 1. As discussed above, Schmieding does not teach or suggest the limitations of independent claim 1 and claim 1 is allowable over Schmieding. Accordingly, because claims 8, 10 and 12 depend from and, therefore, include all of the limitations of independent claim 1, it is respectfully submitted that these claims are also allowable.

As Schmieding's device is a suture anchor in no way suitable for use as an intramedullary nail, the Examiner's assertion that the claimed shapes which enhance the functioning of an intramedullary nail would be a mere design choice ignores the impact such a shape change might have on the actual function of the suture anchors of Schmieding. This speculation by the Examiner is entirely unsupported by the cited reference and it is submitted that the suggested changes are likely to impede the functioning of the suture anchors 2. It is submitted that Schmeiding includes no description that would lead one of skill in the art to believe that such modifications would make the Schmieding device more suited for its purpose or for the purpouse of the present invention and, therefore, that this reference provides absolutely no motivation for the proposed modification. Thus, it is submitted that the modifications proposed by the Examiner constitute improper hindsight reconstructions of the invention.

III. The Rejection of Claims 3 - 6, 11 and 15-16 Under 35 U.S.C. § 103(a) as Obvious over Schmieding Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 3 - 6, 11 and 15-16 were rejected under 35 U.S.C. 103(a) as obvious over Schmieding. (See 2/4/08 Office Action, p. 4). The Examiner stated that Schmieding discloses the claimed invention except for the helix having a rotation of less than 540 degrees, the radius of the cylinder falling in the range of 10 - 50 mm., etc. but that it would have been obvious to have modified the Schmieding device to include these limitations. (*Id.*)

B. Schmieding Does Not Disclose an Intramedullary Nail as Recited in Claim 1

Claim 1 has been recited above and discussed with reference to the 35 U.S.C. § 102(b) rejection. Claims 3 - 6, 11 and 15 - 16 depend from and therefore include all the limitations of independent claim 1. As discussed above, Schmieding does not teach or suggest the limitations of independent claim 1 and claim 1 is therefore allowable. Accordingly, because claims 3 - 6, 11 and 15 - 16 depend from and, therefore, include all of the limitations of independent claim 1, it is respectfully submitted that these claims are also allowable.

IV. The Rejection of Claim 18 Under 35 U.S.C. § 103(a) as Obvious over Schmieding Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claim 18 was rejected under 35 U.S.C. 103(a) as obvious over Schmieding. (See 2/4/08 Office Action, p. 4). The Examiner stated that Schmieding discloses the claimed invention except for the device having at least two through holes but that it would have been obvious to have modified the Schmieding device to include this limitation. (*Id.*)

B. Schmieding Does Not Disclose an Intramedullary Nail as Recited in Claim 1

Claim 1 has been recited above and discussed with reference to the 35 U.S.C. § 102(b) rejection. Claim 18 depends from and therefore includes all the limitations of independent claim 1. As discussed above, Schmieding does not teach or suggest the limitations of independent claim 1 and claim 1 is therefore allowable over Schmieding. Accordingly, it is respectfully submitted that this claim is allowable for the same reasons stated in regard to claim 1.

8. Conclusion

For the reasons set forth above, Appellants respectfully request that the Board reverse the final rejections of the claims by the Examiner under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) and indicate that claims 1 - 18 are allowable.

Respectfully submitted,

Date: July 1, 2008

By: _____
Oleg F. Kaplun (Reg. No. 45,559)

Fay Kaplun & Marcin, LLP
150 Broadway, Suite 702
New York, NY 10038
Tel: (212) 619-6000
Fax: (212) 619-0276

Serial No.: 10/694,846
Group Art Unit: 3733
Attorney Docket No.: 10139 - 04602

CLAIMS APPENDIX

1. (Previously Presented) An osteosynthetic device comprising an intramedullary nail having a longitudinal shape with a central axis, a first end, and a second end, wherein the shape of the device is helical.

2. (Original) The osteosynthetic device of claim 1, wherein the envelope of the helix is a cylinder having the same central axis as the helix.

3. (Previously Presented) The osteosynthetic device of claim 1, wherein the helix has a rotation of less than 540°.

4. (Previously Presented) The osteosynthetic device of claim 1, wherein the radius of the cylinder is in the range of 10 to 50 mm.

5. (Previously Presented) The osteosynthetic device of claim 1, wherein the pitch of the helix is in the range of 100 to 1500 mm.

6. (Previously Presented) The osteosynthetic device of claim 1, wherein the pitch of the helix is greater than 400 mm.

7. (Original) The osteosynthetic device of claim 1, wherein the cross-section orthogonal to the central axis of the helix is a circle.

8. (Original) The osteosynthetic device of claim 1, wherein the cross-section orthogonal to the central axis of the helix is a square or a star.

9. (Original) The osteosynthetic device of claim 1, wherein the second end is pointed.

10. (Original) The osteosynthetic device of claim 1, wherein the cross-section orthogonal to the central axis of the helix is essentially a rectangle with the sides a and b, the larger side b being oriented to the outer and inner sides of the helix.

11. (Previously Presented) The osteosynthetic device of claim 10, wherein the ratio of a:b is smaller than 0.5.

12. (Original) The osteosynthetic device of claim 10, wherein the essentially rectangular cross-section is rounded at its smaller sides a.

13. (Original) The osteosynthetic device of claim 1, wherein the portion of the helix near the first end is thicker than the portion of the helix near the second end.

14. (Original) The osteosynthetic device of claim 1, wherein the central axis of the helix is a straight line.

15. (Previously Presented) The osteosynthetic device of claim 1, wherein the cross-section orthogonal to the central axis has a maximum dimension in the range of 5 to 14 mm.

16. (Previously Presented) The osteosynthetic device of claim 1, wherein the length of the cylinder or of the helix is in the range of 200 to 500 mm.

17. (Original) The osteosynthetic device of claim 1, wherein the device is provided with through holes for locking screws, preferably near the second end.

18. (Previously Presented) The osteosynthetic device of claim 1, wherein the device is provided with at least two through holes for locking screws.

Serial No.: 10/694,846
Group Art Unit: 3733
Attorney Docket No.: 10139 - 04602

EVIDENCE APPENDIX

No evidence has been entered or relied upon in the present appeal.

Serial No.: 10/694,846
Group Art Unit: 3733
Attorney Docket No.: 10139 - 04602

RELATED PROCEEDING APPENDIX

A copy of the Pre-Appeal Brief Review decision is enclosed herewith.